



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,409	03/12/2001	Timothy J. Kieffer	029996/0278721	1113
27500 7590 05/15/2007 PILLSBURY WINTHROP SHAW PITTMAN LLP ATTENTION: DOCKETING DEPARTMENT P.O BOX 10500 McLean, VA 22102			EXAMINER KELLY, ROBERT M	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 05/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/804,409

Applicant(s)

KIEFFER ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 144-155 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 31, 34-36, 38, 40, 43, 47, 49, 51, 54, 55, 71-73, 76, 78, 80, 82, 85-88, 114, 115, 118, 119, and 121-143 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 5/11/07
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 31,34-36,38,40,43,47,49,51,54,55,71-73,76,78,80,82,85-88,114,115,118,119 and 121-155.

Continuation of Disposition of Claims: Claims rejected are 31,34-36,38,40,43,47,49,51,54,55,71-73,76,78,80,82,85-88,114,115,118,119 and 121-143.

Art Unit: 1633

effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, and they have distinct designs, which would lead to distinct modes of operation and effects. The newly claimed invention contains a distinct promoter, which produce a response distinct from that of the other promoters claimed, and therefore, would require distinct search and examination requirements for its effects, structure and function, leading a serious burden on the Examiner to search and examine both inventions together. Moreover, Applicant no longer claims these promoters as broadly as a generic promoter, but only is claiming specific promoters, and hence, the restriction is proper at this time.

Further, it is noted that these inventions are both classified in 514/44, however such classification includes all gene therapy protocols, and therefore this broad classification would necessarily require a distinct search.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 144-155 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Art Unit: 1633

Claims 31, 34-36, 38, 40, 43, 47, 49, 51, 54, 55, 71-73, 76, 78, 80, 82, 85-88, 114, 115, 118, 119, and 121-143 are presently considered.

Claim Status, Cancelled Claims

In light of Applicant's cancellation of Claims 116, 117, and 120, all rejections and/or objections to such claims are rendered moot, and thus, are withdrawn.

Claim Objections

In light of the amendments, the objections to Claims 31, 71, 34-36, 38, 40, 43, 47, 49, 51, 54-55, 72-73, 76, 78, 80, 82, 85-88, and 114, 115, 118, and 119 are withdrawn.

Claims 31, 71, 121, and 133 are objected to because of the following informalities:

Claims 31, 71, 121, and 133 each recite "to stomach or small intestine", while proper English is "to the stomach or the small intestine". However, these claims are not subject to a rejection for lack of antecedent basis as the Artisan would understand the scope of matter encompassed.

Claims 31, 121, and 144 each recite "treating a mammalian subject having diabetes" in the preamble, and further teaches that blood glucose is lowered. As the Artisan would consider such to be for treatment of the diabetes, these claims are not subject to a rejection for lack of clarity, such terminology should be amended in the preambles, and the conclusions, if present, to "treating diabetes in a mammalian subject" so that the claim reflects the intended method, and the conclusions reflect the desired result of the preamble.

Art Unit: 1633

Claims 47, 49, 78, 80, 126, 127, 136, and 137 each recite “cells is present in”, while proper English is “cells are present in”.

Claims 34-36, 38, 40, 43, 49, 51, 54, 55, 71-73, 76, 78, 80, 82, 85-88, 114, 115, 118, 119, 122-132, and 134-143 are objected to for depending from an objected-to base claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – clarity

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In light of the amendments, and the argument providing a clear definition of “undesireable body mass”, the rejections of Claims 31, 34-36, 38, 40, 43, 47, 49, 51, 54-55, 71-73, 76, 78, 80, 82, 85-88, 114, 115, 118, and 119 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn, except for the basis below, as re-explained in terms of the amended claims.

Claim 54, 85, 128, and 139 remain rejected for reciting the limitation “the [promoter] in operable linkage with [the nucleic acid] further comprises a vector”. The metes and bounds of such limitation are unclear. To wit, promoter regions in operable linkage are not generally considered to comprise a vector, but vectors are considered to comprise nucleic acids, which comprise promoters and nucleic acids encoding proteins. Hence, it is unclear if Applicant is claiming a composition of a nucleic acid vector and a separate vector, or whether Applicant is claiming a vector comprising the nucleic acid. However, for purposes of compact prosecution it

Art Unit: 1633

is being interpreted as being substantial duplicates, as Claims 31, 71, 121, 133, 144, respectively, are already drawn to a polynucleotide vector, and the nucleic acid is required to comprise the vector, meaning it is the same overall entity and not a separate component of a composition.

Claim 121 recites "a method of treating a mammalian subject having diabetes", however, the conclusion of the claim is "increases secretion of the insulin by transformed cells in an amount effective to decrease blood glucose in a subject". Without a conclusion indicating that the preamble has been achieved, the method appears to be incomplete, and the Artisan would not know what other steps are required.

Claims 72, 73, 76, 78, 80, 82, 85, 86, 88, 115, 119, 121-132, and 134-143 are rejected for depending from a rejected base claim and not overcoming the lack of clarity in such base claim.

Response to Argument – clarity

Applicant's argument of 3/8/07 has been fully considered but is not found persuasive.

Applicant argues that they have amended the claims to overcome the problems with the vector (p. 13).

Such is not persuasive, given the reasoning provided in terms of the amended claims, above.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Art Unit: 1633

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claims 31, 71, 121, and 133 be found allowable, claims 54, 85, 128, and 139 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The dependent claims, 54, 85, 128, and 139, further limit the independent claims, 31, 71, 121, and 133 by requiring that the polynucleotide be in a vector. However, the independent claims are drawn to a polynucleotide vector. Hence, despite a slight difference in wording, these claims are substantial duplicates of each other.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1633

In light of the amendment and argument, the rejections of Claims 47, 49, 78, and 80 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

Specifically, Applicant has limited the claims to those cell types supported by the specification.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments to the claims, the rejections of Claims 31, 34-36, 38, 40, 43, 47, 49, 51, 54-55, 71-73, 76, 78, 80, 82, 85-88, and 114-120 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

Specifically, by limiting the claims to the tissues, which comprise the cell types, the claims have overcome selectively transforming a specific cell type.

Claim Rejections - 35 USC § 112 – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In light of the amendments and submission of Exhibits E, F, and 1, the rejections of Claims 31, 34-36, 38, 40, 43, 47-49, 51-52, 54-55, 71-73, 76, 78-80, 82-83, and 85-88 under 35

Art Unit: 1633

U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are withdrawn.

Specifically, the amendments and further evidence provided demonstrate that each of the specifically claimed sugars, carbohydrates and amino acids will work.

Claim Rejections - 35 USC § 112 – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 34-36, 38, 40, 43, 47, 49, 51, 54, 55, 71-73, 76, 78, 80, 82, , 85-88, 114, 115, 118, 119, and 121-143 remain and/or are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

(i) A method to treat diabetes in a mammal, the method comprising:

contacting gastrointestinal mucosal tissue cells comprising K cells, stem cells, or multipotent progenitor cells that differentiate into K cells, in a subject, with a polynucleotide vector comprising either (i) a glucose-dependent insulintropic polypeptide (GIP) promoter or (ii) a chromogranin A promoter, operably linked to a nucleic acid sequence encoding insulin via intra-cavity delivery to stomach or small intestine, thereby producing transformed K cells,

wherein subsequently feeding the subject an amount of glucose, sucrose, fructose, carbohydrate, polypeptide, amino acid, or fat increases transcription or secretion of the

Art Unit: 1633

insulin by the transformed cells in an amount effective to decrease blood glucose in the subject, thereby treating the diabetes in the mammalian subject; and

(ii) A method to reduce blood glucose in a mammal having undesirable body mass or obesity, the method comprising:

contacting gastrointestinal mucosal tissue cells comprising K cells, stem cells, or multipotent progenitor cells that differentiate into K cells, in a subject, with a polynucleotide vector comprising a glucose-dependent insulinotropic polypeptide (GIP) promoter, operably linked to a nucleic acid sequence encoding leptin via intra-cavity delivery to stomach or small intestine, thereby producing transformed K cells,

wherein subsequently feeding the subject an amount of glucose, sucrose, fructose, carbohydrate, polypeptide, amino acid, or fat increases transcription or secretion of the leptin by the transformed cells in an amount effective to reduce blood glucose in the subject,

(iii) A method to reduce blood glucose in a mammal having undesirable body mass or obesity, the method comprising:

contacting gastrointestinal mucosal tissue cells comprising gut endocrine cells, stem cells, or multipotent progenitor cells that differentiate into gut endocrine cells, in a subject, with a polynucleotide vector comprising a Chromogranin A promoter, operably linked to a nucleic acid sequence encoding leptin via intra-cavity delivery to stomach or small intestine, thereby producing transformed gut endocrine cells, including K, ECL, G, D, or A-like cells,

Art Unit: 1633

wherein subsequently feeding the subject an amount of glucose, sucrose, fructose, carbohydrate, polypeptide, amino acid, or fat increases transcription or secretion of the leptin by the transformed cells in an amount effective to reduce blood glucose in the subject,

does not reasonably provide enablement for secretion of properly processed insulin from any other than K cells, secretion of leptin from cells other gut endocrine cells, production of leptin by the Chromogranin A promoter in L, S, I, Mo, or GR cells, for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is noted that those arguments provided in the response of 3/8/07, specifically the Wolfe, et al. reference (EXHIBIT 1) demonstrates that secretion can occur in these cells in the absence of transcription and that such was known in the Art to prior to Applicant's priority date, however, the rejection has been modified, to delineate that transcription alone is not reasonably predicted or enabled, for reasons of record.

With regard to administration methods, it is recognized that Applicant has shown a particular plasmid vector that will work to transform stomach (Response of 3/8/07), and that the Artisan would understand that particular administrations may not work, and therefore would avoid those embodiments anyway, therefore making the embodiments for administration reasonably predictable.

With regard to the level of treatment claimed, both for the treatment of diabetes, and the treatment of obese and overweight subjects, the claims are now limited to the treatments that are reasonably predictable.

With regard to the expression of leptin from the Chromogranin A promoter in cells other than , ECL, G, D, or A-like cells, as is of record, these are the only known cells to express genes from the Chromogranin A promoter, and hence, the Artisan would have to experiment to determine those other cells which would so-produce the protein, which is undue, amounting to inventing the breadth of the invention claimed.

However, for reasons of record, it is clear that insulin was only reasonably predicted to be properly processed and secreted from K cells, and therefore, simply producing any of the other cell types would not have been reasonably predicted by the Artisan to produce any therapeutic effect in diabetes. With regard to leptin, as is of record, while leptin is not subject to the processing problems of insulin, the leptin must be secreted and/or produced from cells in response to the various substances, and, as is also of record, the only cells reasonably predicted by the Artisan to produce such results are the gut endocrine cells (a.k.a., mucosal cells of the gut). Hence, these claims remain rejected for the breadth of cell types which are required to be produced (e.g., forming only a stem cell, and not forming the proper endocrine cells for such responses).

Response to Arguments – Enablement

Applicant's arguments filed on 3/8/07 have been fully considered but are not found persuasive.

Art Unit: 1633

Applicant's arguments are strictly drawn to arguments which have been removed from the rejections, and as such, do not address the sole basis of rejection continuing to be held.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In light of the arguments, the rejections of Claims 31, 34, 35, 38, 40, 43, 47, 49, 51, 54-55, 87, 114, 116, and 118 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,503,887 to During and further in view of either Cheung, et al. (2000) Science, 290 : 1959-62 or Hocker, et al. (2001) Gastroenterology, 121: 43-55, are withdrawn.

It is noted that Applicant's filing of 60/188,796 is prior to the publication of both Cheung and Hocker references, and comprises disclosure encompassing both invention (e.g., Claims), such that possession at such time was contemplated, and hence, such art is excluded from the rejections.

Claims 31, 34, 35, 38, 40, 43, 47, 49, 51, 54-55, 87, 114, and 118, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,503,887 to During and Boylan, et al. (1997): Journal of Biological Chemistry, 272(28): 17438-43, of record.

With regard to Claims 31, 34, 38, 40, 43, and 51, During teaches treating patients for IDDM (e.g., col. 1, paragraph 3), by the administration of nucleic acids encoding insulin (e.g.,

Art Unit: 1633

ABSTRACT), which coding sequences are operably linked to tissue-specific promoters (e.g., col. 2, paragraph 5) and may be responsive to glucose (e.g., col. 8, paragraph 3). Such cells include K-cells and L-cells (e.g., col. 7, paragraph 1). Lastly, Claim 1 teaches that any cell of the gut tissue which is an endocrine cell may be used.

With regard to Claims 87 and 114, During teaches the use of various methods of administration, including oral and feed tube feed tube in administration of vector (e.g., cols. 11-12, paragraph bridging).

With regard to vectors, it is noted that During teaches any viral vector (e.g., col. 8, last paragraph and Claim 1), and AAV vectors, which are integrating vectors (e.g., col. 9).

However, During does not teach the GIP promoter, functional subsequences of GIP promoter, fasting glucose above 110mg/dL, or sugars increasing secretion of insulin, although During recognizes that GIP is regulated by glucose (e.g., col. 7, paragraph 3), and teaching that promoters of genes that are regulated by glucose (e.g., col. 8, paragraph 3) and are tissue specific for those cells that secrete the insulin and process it correctly are preferred (e.g., cols. 7-8, paragraph bridging).

On the other hand, Boylan, et al. (1997): Journal of Biological Chemistry, 272(28): 17438-43, e.g., p. 17438 describes the GIP promoter conferring specific expression in, *inter alia*, K cells, as well as the functional subsequences thereof.

With regard to glucose levels, Applicant's own specification teaches that normal levels of glucose levels in plasma are 110 mg/dL, and therefore, it is inherent that the subject with diabetes would have a higher level than 110 mg/dL.

Art Unit: 1633

With regard to response to nutrients, such is not part of the method, and inherent in the treatment, as patients need food to survive, and as such, they would activate the promoter, as well as the fact that GIP was known to be responsive to, inter alia, glucose, and the K cells secrete insulin in response to glucose (e.g., During, col. 7, paragraph 3).

With regard to the various other cell types, those cell types would be inherently treated by the methods of During, because the intestine is generally transformed, and not simply the various cell types. Hence, absent reason to believe otherwise, these other cells are also transformed.

Hence, at the time of invention by Applicant it would have been obvious to modify the treatments of During with the GIP promoter of Boylan. The Artisan would have been motivated to do so in order to treat diabetes, as taught by During. Moreover, the Artisan would have a reasonable expectation of success, as During had taught the method, and Boylan had taught the tissue specific promoters.

Claims 31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,503,887 to During and Boylan, et al. (1997): Journal of Biological Chemistry, 272(28): 17438-43 as applied to claim 31 above, and further in view of Nathan (1999) Annals of Internal Medicine, 120(5): 440-41, published 3/2/99.

As shown above, During and Boylan makes obvious the limitations of claim 1, however, neither During or Boylan or their combination teach or make obvious the treatment of Type 2 Diabetes with insulin, as During is limited to discussion of Type 1 Diabetes.

On the other hand, Nathan teaches that it is and has been known in the Art to treat diabetes by insulin therapies (e.g., p. 440, col. 2, paragraph 2, citing other publications).

Hence, at the time of invention it would have been obvious to modify the methods of During by treating Type 2 diabetics, as taught by Nathan. The Artisan would have been motivated to do so in order to treat the diabetics, as taught by During. Moreover, the Artisan would have had a reasonable expectation of success, as During taught it would work to increase systemic insulin, and Nathan taught that Type 2 diabetics could be similarly treated.

Claims Free of the Art

Claims 71-73, 76, 78, 80, 82, 85, 86, 88, 115, 119, and 121-143 are free of the Art of record.

The closest prior Art for diabetes is that of US PAT NO 6,503,887, to During, teaching treatment of diabetes and obesity by transforming DNES cells, particularly K cells, to secrete insulin. However, prior to the invention by Applicant, the Art did not teach or make obvious the use of the Chromogranin A promoter in K cells, as such was not known to be active in such cells, and as such, there is no reasonable expectation of success using the Chromogranin A promoter with insulin, as it is the K cells which were understood to properly process and secrete insulin, as is of record.

With regard to leptin treatment and the use of vectors encoding either the GIP promoter or Chromogranin A promoter, to express leptin, and thereby reduce blood glucose levels, the closest prior art is that of US PAT NO 6,001,816, to Morsy, which teaches that IV administration of similar vectors can achieve lowered levels of blood glucose (e.g., ABSTRACT). However, such does not teach or make obvious the transformation of gut endocrine cells to express or secrete leptin in response to, inter alia, glucose, thereby being responsive to the various nutrients

Art Unit: 1633

to lower blood glucose on an as-needed basis. Moreover, given the enablement rejections of record, which are further substantiated by Barzon, et al. (2000) European Journal of Endocrinology, 143: 447-66, of record, and teach that such gene therapies with endocrine cells still need to be tested to determine if such will be successful in any particular disease (e.g., p. 460), and given that the Artisan would only have been motivated to treat the obesity in such patients with the leptin treatment, the Artisan could not have had a reasonable expectation of success, given the Art of record.

Conclusion

In light of the citation of new art in the obviousness-type rejection, this rejection is non-final.

No claim is allowed.

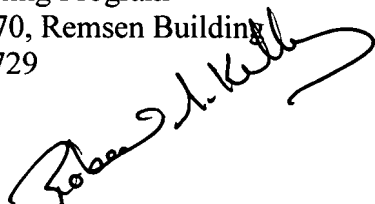
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
Patents Hoteling Program
Mailbox 2C70, Remsen Building
(571) 272-0729

A handwritten signature in black ink, appearing to read "Robert M. Kelly", is written over the printed name and contact information.